REMARKS/ARGUMENTS

Claims 1, 4, 5, 7 to 23 and 26 were previously pending with claim 4 standing withdrawn. Claim 4 is canceled without prejudice. Claims 1 and 14 are presently amended. After entry of these amendments, claims 1, 5, 7 to 23 and 26 to 28 will be pending.

Claims 1, 5 and 7-13 under 35 U.S.C. 112, first paragraph, continue to be rejected for an alleged failure to comply with the written description requirement was maintained.

Claims 1, 5, 7-11, 14-16, 18-23 and 26 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent number 5,955,075.

Claims 1, 5, 7-11, 14-16, 18-23 and 26 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by WO 95/34650 (published December 21, 1995).

Claims 1, 5, 7-23 and 26 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent number 5,955,075 (issued September 21, 19991 IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001.

Claims 1, 5, 7-23 and 26 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1 657, March 15, 2001.

Support for the amendments to the claims

Claims 1 and 14 were amended to set forth SEQ ID NO:2 and steps of obtaining the prognosis and using the prognosis in the selection and design of a treatment regimen for the subject. Support for SEQ ID NO:2 is found in the sequence listing and specification. Support for the use of the prognosis in selection and design of a treatment regimen is found in paragraph 38. New claims 27 and 28 depend from claims 1 and 14, respectively, and set forth wherein the subject has localized renal cell cancer and has a sample quantification percentage below about 85% and the selected and designed treatment regimen is an adjuvant immunotherapy treatment regimen.. Support for this latter subject matter is found *inter alia* in paragraph 35. Accordingly,

the Applicants believe the amendments to the claims add no new matter and respectfully request their entry.

Response to the rejection of claims 1, 5 and 7-13 under 35 U.S.C. 112, first paragraph, for alleged failure to comply with the written description requirement was maintained.

Without acquiescing on the merits and in the spirit of expediting examination, the Applicants have amended claims 1 and 14 to set forth the human carbonic anhydrase IX (CAIX) protein of SEQ ID NO:2. The claims have also been amended to set forth the step of providing a prognosis according to the correlation to the subject. Accordingly, the Applicants respectfully request that the above grounds for rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-11, 14-16, 18-23 and 26 under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent number 5,955,075.

The rejection appears to have been predicated, at least in part, upon disregarding the "correlating" step of the base claims. Without acquiescing on the merits and in the spirit of expediting prosecution, the applicants have amended the base claims to set forth further the active step of "using the prognosis in the selection and design of a treatment regimen for the subject." In addition, in this regard, the Applicants note claims 27 and 28 further set forth that the subject has a localized renal cell cancer and a predicted worse outcome or quantification status and that the selected and designed treatment regimen is an adjuvant immunotherapy treatment regimen.

Further with regard to the correlation's quantification percentage subject matter, the Applicants note again that, as the '075 patent teaches MN as a putative oncogene (*see*, '075 patent at col. 4, lines 5 to 9), the skilled person would understand that for diagnosis, high levels of CAIX may imply a high probability of renal cell carcinoma and that the higher the level of expressed CAIX present, the more damage is done. However the claims of the present application are all drawn to methods of prognosis (i.e., forecasting the probable outcome of the disease state) based upon the present inventors' discovery that unexpectedly high levels of CAIX

indicated a *better*, not worse, chance for recovery. This particular surprising relationship and its practical application in prognosis was not taught or suggested in the cited art.

Accordingly, the Applicants respectfully request that the above grounds for rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-11, 14-16, 18-23 and 26 under 35 U.S.C. 102(b) as allegedly being anticipated by WO 95/34650.

The rejection appears to have been predicated, at least in part, upon disregarding the "correlating" step of the base claims. Without acquiescing on the merits and in the spirit of expediting prosecution, the applicants have amended the base claims to set forth the further step of obtaining a prognosis for the subject based upon a correlation wherein the prognosis for a subject having a sample quantification percentage below about 85% is worse than the prognosis for a subject having a sample quantification above 85%.

Further with regard to the correlation subject matter, the Applicants note again that, as the WO 95/34650 publication teaches MN as a putative oncogene (*see*, first line of the Abstract, the skilled person would understand that for diagnosis, high levels of CAIX may imply a high probability of renal cell carcinoma and that the higher the level of expressed CAIX present, the more damage is done. However the claims of the present application are all drawn to methods of prognosis (i.e., forecasting the probable outcome of the disease state) based upon the present inventors' discovery that unexpectedly high levels of CAIX indicated a *better*, not worse, chance for recovery. This particular, surprising relationship and its practical application in selecting and designing a therapy was not taught or suggested in the cited art.

Accordingly, the Applicants respectfully request that the above grounds for rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-23 and 26 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent number 5,955,075 (issued September 21, 19991 IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001.

Zisman et al. teach an integrated staging system for prognostication of renal cell carcinoma. They do not mention CAIX. The Examiner contends a reasonable expectation of success would be present in the proposed combination. As noted above, the expectation would have been that an increased CAIX expression would have been associated with the worse prognosis. Here, the claims set forth just the *opposite* relationship. As the instant invention is not a case where prior art elements were combined according to known methods to yield *predictable* results (see, MPEP §2143), the Applicants respectfully request that this grounds of rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-23 and 26 under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1 657, March 15, 2001.

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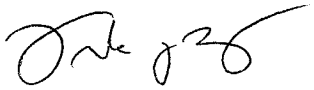
CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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